

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 37697-0035

In re patent application of

Edward W. MERRILL *et al.*

Serial No.: To be assigned

Filed: Concurrently herewith

For: Radiation and Melt Treated Ultra High Molecular Weight  
Polyethylene Prosthetic Devices

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination, please enter the following amendments.

**IN THE SPECIFICATION**

Page 1, please delete the text at lines 3-10 in its entirety and insert the following:

This application is a continuation of U.S. Serial No. 09/572,324, filed May 18, 2000, which is a continuation of U.S. Serial No. 08/798,638, filed February 11, 1997, which is a continuation-in-part of 08/726,313, filed October 2, 1996, which is a continuation-in-part of U.S. Serial No. 08/600,744, filed February 13, 1996, which issued as U.S. Patent No. 5,879,400. The entire contents of each of the above-identified applications are hereby incorporated by reference.

**IN THE CLAIMS**

Please cancel claims 1-123 without prejudice or disclaimer. Please add the claims set forth below.

124. (New) A medical prosthesis for use within the body, said prosthesis being formed of radiation treated ultra high molecular weight polyethylene having cross-links and multiple melting peaks.

125. (New) The medical prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has three melting peaks.

126. (New) The medical prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has two melting peaks.

127. (New) The medical prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has been subjected to heating by irradiation.

128. (New) The medical prosthesis of claim 124, wherein said polymeric structure has extensive cross-linking so that a substantial portion of said polymeric structure does not dissolve in xylene at 130°C or decalin at 150°C over a period of 24 hours.

129. (New) The medical prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has an initial average molecular weight of greater than about 1 million.

130. (New) The medical prosthesis of claim 124, wherein said prosthesis is constructed and arranged for replacement of a joint selected from the group consisting of a hip joint, a knee joint, an elbow joint, a shoulder joint, an ankle joint and a finger joint.

131. (New) The prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity and less than about 940 MPa tensile elastic modulus, so as to reduce production of fine particles from said prosthesis during wear of said prosthesis.

132. (New) Radiation treated ultra high molecular weight polyethylene having multiple melting peaks and cross-links.

133. (New) The ultra high molecular weight polyethylene of claim 132, wherein said ultra high molecular weight polyethylene has three melting peaks.

134. (New) The ultra high molecular weight polyethylene of claim 132, wherein said ultra high molecular weight polyethylene has two melting peaks.

135. (New) The ultra high molecular weight polyethylene of claim 132, wherein said ultra high molecular weight polyethylene has been subjected to heating by irradiation.

136. (New) The ultra high molecular weight polyethylene of claim 132, wherein said ultra high molecular weight polyethylene has a unique polymeric structure characterized by less than about 50% crystallinity and less than about 940 MPa tensile elastic modulus.

137. (New) A method for making a cross-linked ultra high molecular weight polyethylene having multiple melting peaks, comprising the steps of: providing ultra high molecular weight polyethylene having polymeric chains; irradiating said ultra high molecular weight polyethylene so as to cross-link said polymeric chains; and cooling said heated ultra high molecular weight polyethylene.

138. (New) The method of claim 137, wherein said ultra high molecular weight polyethylene in said providing step is heated to a temperature above room temperature but below the melting temperature of said ultra high molecular weight polyethylene.

139. (New) A method for making across-linked ultra high molecular weight polyethylene, comprising the steps of: providing ultra high molecular weight polyethylene having polymeric chains that is at room temperature or below room temperature; irradiating said ultra high molecular weight polyethylene so as to (1) cross-link said polymeric chains and (2) to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene; and cooling said heated ultra high molecular weight polyethylene.

140. (New) A method for making cross-linked ultra high molecular weight polyethylene, comprising the steps of: providing ultra high molecular weight polyethylene at a temperature of no more than about 90°C; irradiating said ultra high molecular weight polyethylene to cross-link the ultra high molecular weight polyethylene and to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene; and cooling said irradiated ultra high molecular weight polyethylene.

141. (New) A method for making cross-linked ultra high molecular weight polyethylene, comprising the steps of: providing ultra high molecular weight polyethylene at a temperature ranging from about 90°C to below the melting point; irradiating said ultra high molecular weight polyethylene to cross-link the ultra high molecular weight polyethylene and to generate sufficient heat to at least partially melt

the ultra high molecular weight polyethylene; and cooling said irradiated and heated ultra high molecular weight polyethylene.

142. (New) A method for making a cross-linked ultra high molecular weight polyethylene having substantially no detectable free radicals, comprising the steps of: providing ultra high molecular weight polyethylene having polymeric chains, wherein the ultra high molecular weight polyethylene is at a temperature below its melting point; irradiating said ultra high molecular weight polyethylene with more than 5 Mrads of radiation so as to cross-link said polymeric chains; and cooling said heated ultra high molecular weight polyethylene.

143. (New) The method of claim 142, wherein the final temperature of said ultra high molecular weight polyethylene after said irradiation step is above the melting temperature of said ultra high molecular weight polyethylene.

144. (New) A method of making a medical prosthesis from radiation treated ultra high molecular weight polyethylene having multiple melting peaks, said prosthesis resulting in the reduced production of particles from said prosthesis during wear of said prosthesis, comprising the steps of: providing radiation treated ultra high molecular weight polyethylene having multiple melting peaks; and forming a medical prosthesis from said ultra high molecular weight polyethylene so as to reduce production of

particles from said prosthesis during wear of said prosthesis, said ultra high molecular weight polyethylene forming a load bearing surface of said prosthesis.

145. (New) A method of making a medical prosthesis from radiation treated ultra high molecular weight, said prosthesis resulting in the reduced production of particles from said prosthesis during wear of said prosthesis, comprising the steps of: providing ultra high molecular weight polyethylene that has been irradiated above room temperature at a dose rate of at least 2 Mrads/hour; and forming a medical prosthesis from said ultra high molecular weight polyethylene so as to reduce production of particles from said prosthesis during wear of said prosthesis, said ultra high molecular weight polyethylene forming a load bearing surface of said prosthesis.

146. (New) A method of making a medical prosthesis from radiation treated ultra high molecular weight, said prosthesis resulting in the reduced production of particles from said prosthesis during wear of said prosthesis, comprising the steps of: providing ultra high molecular weight polyethylene that has been irradiated above room temperature at a dose rate of at least 4 Mrads/hour; and forming a medical prosthesis from said ultra high molecular weight polyethylene so as to reduce production of particles from said prosthesis during wear of said prosthesis, said ultra high molecular weight polyethylene forming a load bearing surface of said prosthesis.

147. (New) A method for making a cross-linked polyethylene, comprising the steps of: providing polyethylene at a temperature that is below the melting point; irradiating the polyethylene so as to (1) cross-link said polymeric chains and (2) to generate sufficient heat to at least partially melt the polyethylene; and cooling said heated polyethylene.

148. (New) The method according to claim 147, wherein the irradiation melts the polyethylene.

149. (New) The method according to claim 147, wherein a heating source in addition to radiation melts the polyethylene.




**REMARKS**

Applicants have canceled claims 1-123 without prejudice or disclaimer of the subject matter recited therein, and applicants expressly reserve all rights to such subject matter. Applicants have added claims 124-149. Applicants request examination of the claims. A first office action on the merits is awaited.

Respectfully submitted,

April 26, 2001  
Date

  
\_\_\_\_\_  
John P. Isacson  
Reg. No. 33,715

HELLER EHRMAN  
WHITE & McAULIFFE LLP  
1666 K Street, N.W., Suite 300  
Washington, D.C. 20006  
Tel: 202-912-2000  
Fax: 202-912-2020



26633